



# Equitable Division of International Joint Costs in Pharmaceutical Research and Development

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# Equitable Division of International Joint Costs in Pharmaceutical Research and Development

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Food and Drug Law Third-Year Paper

Significant increases in pharmaceutical spending over the past two decades have lead to public outrage over the cost of prescription drugs. Pharmaceutical research and development is an expensive process – in 2000 it was estimated that drug companies spent more than \$800 million in R&D for each new chemical entity that was brought to market. These R&D costs should be divided across all users of the new drugs. However, due to the widespread use of cost controls in other countries, on average Americans pay 40% to 125% more for a prescription drug than foreign citizens. Foreign governments are pushing a disproportionate amount of drug research costs onto American citizens – Americans believe they are subsidizing health care for the rest of the world.

The outrage over high U.S. prescription drug prices has lead to a growing movement in the United States to allow reimportation of drugs from other countries. Unfortunately, while reimportation may reduce price disparities between the U.S. and other nations, it will do so by importing the inefficient cost control regulations present in other countries.

Economic theory suggests that cost controls are necessary in pharmaceutical markets due to the threat of moral hazard. Cost controls eliminate market distortions and can be economically beneficial for both drug firms and pharmaceutical consumers. However, imposing cost regulations can be dangerous if the cost cuts are too deep. Regulatory systems charged with cutting drug prices are motivated to ignore the large sunk costs of R&D and set drug prices at the marginal cost of serving their population – which can often be as little as 25% of the cost of a drug. Further, the global benefits of pharmaceuticals create a free-rider problem where governments can achieve the benefits of new drug developments without having to pay the associated costs of researching that drug.

This paper outlines an international approach that will allow drug manufacturers to equitably recoup global joint research costs, while recognizing the international need for constraints on prescription drug spending. Due to the prisoner's dilemma associated with government pricing of prescription drugs, the only way to ensure an equitable distribution of R&D expenditures is with a comprehensive treaty that limits the forms of cost controls each member nation can impose. The treaty, which is based on the British system of regulating pharmaceutical company profit margins, ensures that each country contributes a minimum share of the joint costs associated with the development of a pharmaceutical. Global R&D costs are allocated between member nations based on a formula that accounts for the level of prescription usage in each country and that accounts for the financial ability of a country to fund global drug development. However, the treaty allows member nations significant discretion to curtail drug prices by regulating advertising, manufacturing, regulatory, liability, and other drug costs.

## Section I. Introduction.

Though there have been repeated calls to impose price regulations on prescription drugs since the 1960's, the debate has taken on a new priority and many now think change is finally on the way.<sup>1</sup> The convergence of several different factors has lead Americans to the conclusion that regulation of the industry is now necessary. The first factor is the rapidly rising cost of prescription drugs. Prescription drug spending in the United States has risen more than 12.2 percent annually between 1980 and 2002.<sup>2</sup> Further, prescription drug spending is projected to increase by 7.4 percent annually over the next ten years – far outpacing the rate of inflation.<sup>3</sup> With costs rising so rapidly, at least 75 million people, or 27 percent of the U.S. population, do not have prescription drug coverage.<sup>4</sup>

Further, while Americans are laboring to pay the rising costs of prescription drugs, pharmaceutical companies are recording record profits. Pharmaceutical and biotechnology companies have posted average profit margins of between 20 and 25 percent since 1999.<sup>5</sup> These companies have outperformed the S&P 500 every year for the past five years.<sup>6</sup>

The final, and probably most important, factor driving the call for regulating prescription drug costs is the significant disparity between American prices and prices in foreign countries. Every industrialized country except

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<sup>1</sup> See, e.g., *Bush Administration Reconsidering Canadian Drugs*, May 7, 2004, YAHOO NEWS, at [http://news.yahoo.com/news?tmpl=story&u=/ibsys/20040507/lo\\_wisc/2196499](http://news.yahoo.com/news?tmpl=story&u=/ibsys/20040507/lo_wisc/2196499) (Secretary of HHS acknowledges drug reimportation is inevitable and President Bush should not stand in the way).

<sup>2</sup> Data taken from CMS tables. See CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS), 2002 NATIONAL HEALTH CARE EXPENDITURES PROJECTIONS TABLES, at table 2, available at <http://www.cms.hhs.gov/statistics/nhe/projections-2002/t2.asp>; CMS, 2003 NATIONAL HEALTH CARE EXPENDITURES PROJECTIONS TABLES, at table 2, available at <http://www.cms.hhs.gov/statistics/nhe/projections-2003/t2.asp>.

<sup>3</sup> See CMS, 2003 NATIONAL HEALTH CARE EXPENDITURES PROJECTIONS TABLES, at table 2, available at <http://www.cms.hhs.gov/statistics/nhe/projections-2003/t2.asp>.

<sup>4</sup> The Congressional Budget Office estimated about 60 million nonelderly Americans did not have insurance for at least part of 1998. See Congressional Budget Office (CBO), *How Many People Lack Health Insurance and For How Long?* (May 2003), available at <ftp://ftp.cbo.gov/42xx/doc4210/05-12-Uninsured.pdf>. Also, 47 percent of the 31.1 million Medicare beneficiaries did not have coverage for prescriptions. See Department of Health and Human Services (HHS), *Prescription Drug Coverage, Spending, Utilization, and Prices* (April 2000), available at <http://aspe.hhs.gov/health/reports/drugstudy/>.

<sup>5</sup> See CMS, *HEALTH CARE INDUSTRY MARKET UPDATE: PHARMACEUTICALS* (January 10, 2003), at 4, available at <http://www.cms.hhs.gov/reports/hcimu/hcimu.01102003.pdf>.

<sup>6</sup> See id. at 24.

for the U.S. imposes some form of government cost control on prescription drug expenditures. As a result, average prices for patented prescription drugs are 40 to 125 percent higher in the United States than they are in other industrialized countries.<sup>7</sup> U.S. consumers believe they are subsidizing health care for the rest of the world – they are now pushing for cost control measures that will eliminate this unfair price disparity.

So far, lawmakers are reluctant to mandate that the government directly negotiate prices with pharmaceutical companies, as many other foreign governments do.<sup>8</sup> Reform efforts have instead focused on using private health insurers and managed care providers to negotiate lower prices on behalf of the government. At the same time, lawmakers want to legalize the reimportation of drugs from overseas to help reduce international price discrepancies.<sup>9</sup> Congress believes it is preferable to resolve this dilemma with market-based reforms rather than by resorting to broad, direct government regulation.<sup>10</sup>

On the other hand, pharmaceutical companies argue that current drug prices are necessary to recoup the significant research and development expenses associated with bringing a new drug to market. A recent study concluded that pharmaceutical companies spend an average of \$800 million for each new chemical entity (NCE) that is brought to market.<sup>11</sup> Two significant components of these R&D expenditures are the cost of investigating failed compounds and the cost of capital associated with the average twelve-year lag from concept to launch.<sup>12</sup>

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<sup>7</sup> This estimate is based on the discounted prices that the federal government and large private insurers are able to negotiate with drug manufacturers – price differentials for retail customers are even greater. See CBO, WOULD PRESCRIPTION DRUG IMPORTATION REDUCE U.S. DRUG SPENDING? (April 29, 2004), available at <http://www.cbo.gov/showdoc.cfm?index=5406&sequence=0>.

<sup>8</sup> Jackie Koszczuk, *Medicare overhaul leaves questions about how to control rising drug prices*, CQ WEEKLY (Dec. 6 2003), at 3034.

<sup>9</sup> See Kate Schuler, *Republicans taking a second look at drug reimportation proposals*, CQ WEEKLY (Apr. 17 2004), at 909.

<sup>10</sup> See *id.*

<sup>11</sup> See Joseph A. DiMasi, et al., *The price of innovation: New estimates of drug development costs*, 22 JOURNAL OF HEALTH ECONOMICS 151 (2003). Another estimate by the public interest group Public Citizen places the cost of each new drug at \$110 million. See PUBLIC CITIZEN, RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY'S R&D "SCARE CARD" (2003). However, this study is based on 1993 cost estimates and does not apply a discount rate to costs based on costs of capital. Further, the study includes drug applications for reformulations and for treating new indications, not only applications for NCE's. Finally, the study does not accurately account for the costs associated with the testing of failed compounds. See *id.*

<sup>12</sup> See PATRICIA M. DANZON, PHARMACEUTICAL PRICE REGULATION 5 – 6 (1997).

Research expenditures account for more than 30% of the cost of a new drug therapy while the marginal cost of serving another pharmaceutical customer can be as little as 25% of the cost of a new drug.<sup>13</sup> Due to the large sunk costs and low marginal costs associated with a drug therapy, government regulation can have disastrous consequences. Accordingly, government cost control regulations are biased towards reducing drug prices to the marginal cost of serving that nation's population.<sup>14</sup> Governments can save money by pushing the joint costs of research, which should be borne equally by all users,<sup>15</sup> onto the citizens of foreign governments. As such marginal cost pricing becomes widespread, the inability of pharmaceutical companies to recover their sunk research costs will reduce incentives for future research into innovative drugs. The short-term price reductions come at the potential cost of failing to develop innovative new therapeutics that could save countless numbers of lives.<sup>16</sup>

Despite the potential dangers associated with government-imposed cost regulations, in a single-payer health care system, these cost controls can play an economically beneficial role by reducing moral hazard.<sup>17</sup> Governments must therefore maintain a balance between the need to impose cost controls and the need to maintain incentives for future pharmaceutical research.<sup>18</sup>

This article begins by briefly describing the health care industry and the economics of the drug industry in Part II. Part III then describes and analyzes pharmaceutical cost control regimes used by foreign governments. Part IV then looks at recent proposals calling for the reimportation of drugs into the U.S. After concluding that drug reimportation will not fairly allocate the joint costs of pharmaceutical research, Part V presents an alternate international framework for effectively allocated these joint costs. The framework calls for an international treaty that will restrict the type and extent of cost control regulations that member nations can enact.

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<sup>13</sup> See *id.* at 3.

<sup>14</sup> See *id.*

<sup>15</sup> As discussed later, ideally joint costs should not actually be shared equally but rather should be allocated in proportion to the willingness to pay. See *infra* Part II.2.

<sup>16</sup> See DANZON, *supra* note 12, at 3.

<sup>17</sup> See *infra* Part II.

<sup>18</sup> See DANZON, *supra* note 12, at 6.

## Part II. Pharmaceutical market structure and the effects of price controls.

### 1. Structure of the health care market

The structure of health care markets is important because it affects how pharmaceutical companies are able to reap the benefits of their innovations. The United States is one of a few nations whose health care system is a true mix of private and public health care plans.<sup>19</sup> The main players in the U.S. public health care system are Medicare and Medicaid. Approximately 5 percent of the U.S. population is covered through Medicare and 9 percent is covered through Medicaid.<sup>20</sup> Medicare is a federal program that provides health care coverage for the elderly and disabled. Medicare is operated as an indemnity program – that is the program does not employ its own physicians or hospitals. Instead, patients are treated by private physicians and use private hospitals that have been pre-approved by the program. The Medicare program then reimburses these private parties a predetermined fee for the services they provide to Medicare patients. Medicare is funded through a combination of employment tax revenues, general revenues, and premiums paid by the individuals receiving coverage.<sup>21</sup> While Medicare covers inpatient drugs, it does not yet have outpatient prescription drug coverage.<sup>22</sup>

Medicaid is a state-funded program that provides coverage for the poor. This program is also operated as an indemnity program. The program maintains its own list of approved doctors and hospitals and sets a fixed reimbursement rate for services, just as Medicare does. Medicaid however offers an outpatient prescription drug benefit. Medicaid beneficiaries usually obtain pharmaceuticals from a retail pharmacy. The program then reimburses the pharmacies a fixed price to cover the cost of the drugs.<sup>23</sup>

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<sup>19</sup> See ALBERT WERTHEIMER, *et al.*, *Pharmacy in the Western World Health Care Systems*, in *CONTESTED GROUND* 159, 169 (Peter Davis ed., 1996).

<sup>20</sup> See CMS, HEALTH CARE SYSTEM: FACTS AND FIGURES, at table 1.4, available at <http://www.cms.hhs.gov/charts/healthcaresystem/>.

<sup>21</sup> See WERTHEIMER, *supra* note 19, at 169-170.

<sup>22</sup> Prescription drug coverage under the Medicare Act does not begin till 2006. PUB. LAW NO. 108-173 (Dec. 8 2003).

<sup>23</sup> See WERTHEIMER, *supra* note 19, at 169-170.

The U.S. health care system also consists of two basic types of private health care plans – conventional indemnity plans and health maintenance organizations (HMO).<sup>24</sup> An indemnity program works the same way as Medicare; an insurance company reimburses a service provider for medical care rendered. Patients might or might not be required to see pre-approved providers, depending on the specifics of the plan. HMOs, on the other hand, are much more integrated than traditional indemnity programs. HMOs aim to reduce costs by closely managing the services hospitals and physicians provide to beneficiaries. Often, the HMOs will directly own the hospitals and directly employ the physicians providing services. In exchange for lower premiums, HMOs usually have more restrictions on the level of service provided and more restrictions on the choice of service providers.<sup>25</sup> Prescription drug coverage in these private programs varies from plan to plan, however almost all plans have some level of drug coverage.<sup>26</sup> Currently, about 70% of Americans are enrolled in a private health insurance plan,<sup>27</sup> and 23% of these private plan beneficiaries are in HMO plans.<sup>28</sup> There has been a long-term trend away from indemnity plans towards HMOs.<sup>29</sup> Unfortunately, 16% of the U.S. population has no health care insurance coverage.<sup>30</sup> Unlike the U.S., most foreign countries guarantee health care coverage for all citizens.<sup>31</sup> Government can provide universal health care coverage through one of two methods, either through a national health insurance program (NHI) or through a national health service (NHS) program. Most countries operate a form of NHI.<sup>32</sup> NHI beneficiaries receive services at private hospitals and clinics, and the government reimburses these expenses through tax revenue. On the other hand, an NHS system is operated more like an HMO. The British and Canadian systems resemble this NHS structure. The government often owns the hospitals and clinics and directly employs physicians

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<sup>24</sup> See *id.* *Conventional indemnity plans here also includes PPO and POS systems which are basic indemnity plans that have some HMO-like qualities.*

<sup>25</sup> See *id.*

<sup>26</sup> See KAISER FAMILY FOUNDATION (KFF), *SURVEY OF EMPLOYER HEALTH BENEFITS (1999)*, available at <http://www.kff.org/insurance/index.cfm>.

<sup>27</sup> See CMS, *supra* note 20, at table 1.4. Figure does not include Medicare beneficiaries enrolled in private supplemental insurance plans.

<sup>28</sup> See *id.* at table 4.11.

<sup>29</sup> See *id.*

<sup>30</sup> See *id.* at table 1.4.

<sup>31</sup> See WERTHEIMER, *supra* note 19, at 170.

<sup>32</sup> See *id.*



and other health care workers. The government administers the whole system and funds operation of the system through tax revenues.<sup>33</sup>

In the United States, there are two major government health care programs and many different private programs. These programs directly reimburse pharmaceutical companies for the cost of prescription drugs. However, most foreign countries have universal health care systems. In both types of universal health care programs, the government is the sole health care plan provider and is the sole entity that reimburses pharmaceutical companies for prescription drugs. These governments are monopsonists, the opposite of monopolists, because they are the only purchasers of a product rather than the only supplier.<sup>34</sup> These monopsonist systems are also termed single-payer systems. The governments can use their market power as monopsonists to impose stringent cost controls for prescription drugs. While large U.S. service providers are also able to negotiate discounts with pharmaceutical companies, no U.S. provider is large enough to exercise as much power as a single-payer foreign government. The presence of a single-payer system has significant effects on prescription drug pricing, as we will see later.<sup>35</sup>

## 2. Cost structure of a pharmaceutical

In 2000, the average cost of bringing a new pharmaceutical<sup>36</sup> to market was more than \$800 million.<sup>37</sup> Drugs that are ranked by the FDA as the most innovative have even higher development costs.<sup>38</sup> The pharmaceutical drug industry invests enormous amounts of money in R&D – almost 18% of sales in 1994.<sup>39</sup> However, this number significantly understates the true cost of R&D, since the average NCE requires 12 years of R&D before being

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<sup>33</sup> See *id.*

<sup>34</sup> See *id.*

<sup>35</sup> See *infra Part II.4.*

<sup>36</sup> Meaning a NCE, or new chemical entity. The cost R&D cost does not include reformulations and the application of existing drugs to new indications.

<sup>37</sup> See *DiMasi, supra note 11, at 169.*

<sup>38</sup> See *DANZON, supra note 12, at 7.*

<sup>39</sup> See CBO, *HOW HEALTH CARE REFORM AFFECTS PHARMACEUTICAL RESEARCH AND DEVELOPMENT (June 1994), at ix.*

brought to market.<sup>40</sup> As listed in **Table 1**, when all costs associated with a drug are converted to present value at the time of launch, R&D accounts for 30% of a drug's cost, while the marginal cost of manufacturing is only 25% of the drug's total cost.

Table 1. Pharmaceutical cost structure: Discounted present value at launch (percent of total cost after tax) <sup>41</sup>		
Tax Assumptions		
Cost component		tax
Total R&D Cost	31.1	29.7
	R&D sunk costs	29.0
	Ongoing R&D costs	2.1

<sup>40</sup> See OFFICE OF TECHNOLOGY ASSESSMENT (OTA), PHARMACEUTICAL R&D: COSTS, RISKS, AND REWARDS (1993).  
<sup>41</sup> Chart taken from DANZON, *supra* note 12, at 6.

Total Man- u- fac- tur- ing Cost	28.2	28.7	
	Manufacturing and distribution	25.3	
	Capital ex- pen- di- tures	2.9	
Other			
	Marketing costs	23.4	
2.6			
Total	100.0	100.0	

Note: Assumes 10% cost of capital.

The development costs associated with bringing a drug to market are sunk costs – that is, the pharmaceutical companies have already incurred the expenditures at the time the product is launched. Pharmaceutical companies

must rely on the patent system to recover these sunk costs. Once a company has discovered a drug treatment, in the absence of patent protection, any drug company can manufacture and market a generic version of that drug. While the pharmaceutical company must sell the drug at a price that allows the company to recoup its sunk R&D costs, the generic manufacturer has not incurred these sunk costs. The generic manufacturer can thus sell the drugs at a much cheaper price, as much as 30% cheaper, as illustrated by **Table 1**. The patent system protects pharmaceutical companies by granting them market exclusivity for a limited period of time.<sup>42</sup> The drug companies can recoup their sunk R&D expenses during the patent period without fear of competition from generic manufacturers.

### ***3. Optimal pricing for pharmaceuticals***

The high ratio of sunk costs to marginal costs presents a challenge for pharmaceutical companies. The patent system helps resolve this challenge by granting pharmaceutical companies a limited monopoly. Pharmaceutical companies must then price their products in a manner so as to maximize profits from this limited monopoly. In most industries, producers charge every customer the same price for a given good.<sup>43</sup> However, uniform pricing results in a large deadweight loss for pharmaceuticals companies, as illustrated by **Figure 1**. Consumers who are willing to pay more for prescription drugs will pay less than their true marginal benefit. Consumers who are less willing to pay for prescriptions will face a price that exceeds their budget and will therefore drop out of market – even though those consumers may have been willing to pay a price higher than the marginal cost of production.<sup>44</sup> The two lined areas represent a deadweight loss. A drug has created a social surplus, but companies are unable to collect value from the created surplus. Since pharmaceuti-

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<sup>42</sup> See DANZON, *supra* note 12, at 8.

<sup>43</sup> See *id.* at 11.

<sup>44</sup> See *id.*

cal companies face this deadweight loss, many otherwise socially beneficial drugs<sup>45</sup> will never be developed because companies will not be able to recover the expenses associated with research and development.<sup>46</sup>

Marginal Cost

Quantity

Price



Demand Curve

Figure 1. Total revenue collected under a uniform pricing model.

The economist Frank Ramsey developed a more optimal pricing scheme.<sup>47</sup> For industries with high sunk costs and low marginal costs, Ramsey argued the most efficient pricing mechanism is to charge consumers different prices based on their relative price elasticities – firms should charge more to consumers that are willing to pay more. The principle of price discrimination is applied in other industries with high joint costs, such as utilities and airlines.<sup>48</sup> Peak-time users pay more for electricity than off-peak users. Similarly, people who book flights in advance and accept minimum stay requirements or other restrictions pay less for airline flights.

Accordingly, pharmaceutical firms should charge higher prices to consumers that are more willing to pay those higher prices, and should charge lower prices to consumers that are not willing to pay the high prices. Differential

<sup>45</sup> That is, drugs whose development cost is less than the social value they create.

<sup>46</sup> See *id.* at 11.

<sup>47</sup> See *Frank Ramsey, A contribution to the theory of taxation*, 37 *ECONOMIC JOURNAL* 47-61 (1927).

<sup>48</sup> See DANZON, *supra* note 12, at 11.

pricing, as depicted in Figure 2, raises total revenue because now those consumers with a higher valuation pay more for their prescriptions and those customers with lower valuations now purchase the prescription and contribute to revenue. This reduces or eliminates the amount of deadweight loss. A differential pricing scheme maximizes social welfare because pharmaceutical firms will develop all drugs with a net positive social value – that is all drugs whose benefits outweigh their costs.<sup>49</sup>



Marginal Cost

Demand Curve

Price



Quantity

Figure 2. Increased total revenue under a differential pricing model.

Not only is differential pricing more economically efficient than uniform pricing, it is also more socially beneficial. Consumers who would not be able to afford a pharmaceutical in the uniform pricing model will now have access to the drug. Also, since costs are spread out over more people and are allocated with respect to each consumer's willingness to pay, differential pricing results in a more equitable distribution of the costs associated with research and development.

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<sup>49</sup> See *id.* at 12.

#### 4. Market distortions under indemnity insurance systems

The Ramsey pricing model describes the optimal pricing method in a competitive market. However, due to distortions in the pharmaceutical market caused by the presence of indemnity insurance programs, the Ramsey model of differential pricing is not feasible and another framework must be adopted to determine optimal pricing. Most citizens in developed countries have health care through an indemnity insurance program. 84% of Americans have some form of insurance coverage and most other developed countries have universal indemnity coverage.<sup>50</sup> The presence of indemnity insurance systems, and especially single-payer indemnity systems, creates two distortions in the pharmaceutical market – uniform pricing and moral hazard.

##### **Uniform pricing**

The presence of an insurer creates a market distortion because the insurer will reimburse the same price for all beneficiaries that fill a prescription. Since customers now purchase pharmaceuticals in groups, it is more difficult for pharmaceutical companies to apply differential pricing. The effect is most pronounced under single-payer systems. Since the government insures all residents of the country, a pharmaceutical company will be reimbursed the same price for all prescriptions sold in that country. As a consequence of charging a uniform price, there will be a deadweight loss as illustrated in Figure 1 above.<sup>51</sup>

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<sup>50</sup> See *supra* Part II.1.

<sup>51</sup> See *supra* Part II.3.

## Moral hazard

The use of indemnity insurance creates a second distortion, moral hazard. Moral hazard is characteristic of every indemnity insurance market.<sup>52</sup> Moral hazard is the tendency for an individual's behavior to change because of the presence of insurance coverage.<sup>53</sup> For instance, an individual that is covered by insurance may undertake more risky behavior than he would without insurance because he knows that the ultimate cost of his risky behavior will fall on his insurer and not come out of his own pocket. Similarly, when a patient is admitted to the hospital, he may choose to stay longer than necessary because he knows the insurance company will pay for the stay.

Moral hazard can be divided into two types, consumer moral hazard and producer moral hazard.<sup>54</sup> Consumer moral hazard occurs when an insured patient demands more medical services than he would if he were paying for those services himself.<sup>55</sup> Consumer moral hazard can be further divided into two subcategories: ex ante and ex post moral hazard. Ex ante moral hazard occurs when a patient in a healthy state fails to take the appropriate preventive measures prior to sickness because the patient will not have to bear the costs of treating the sickness. For example, a patient is less likely to eat healthy and exercise if he knows that an insurer will cover the cost of cholesterol-reducing statin drugs. Conversely, ex post moral hazard occurs when the patient is already ill. A patient is more likely to obtain a prescription rather than consuming a cheaper over-the-counter drug if an insurer pays for the prescription drug.

Consumer moral hazard is dangerous because it leads to an excessive demand for prescription drugs – more pharmaceuticals are consumed than would be expected under normal market conditions.<sup>56</sup> There is a welfare loss

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<sup>52</sup> See ATIF AHMAD, WHAT IS MEANT BY MORAL HAZARD? (2002), at [http://www.econ.qmw.ac.uk/NHS\\_reforms.com/student\\_file/insurance2](http://www.econ.qmw.ac.uk/NHS_reforms.com/student_file/insurance2).

<sup>53</sup> See id.

<sup>54</sup> See id.

<sup>55</sup> See id.

<sup>56</sup> See id.



to society since the costs of prescription drugs exceed their benefits to patients.<sup>57</sup> This welfare loss is indicated in **Figure 3** by the dotted area. Assuming the insurer pays a fixed cost for the drug it reimburses, the dotted area represents extra costs born by the insurer due to the presence of moral hazard. Without the presence of insurance, the patients indicated in the dotted area would never have purchased the prescription drug.

Price

Demand Curve

Price paid by insurer

Quantity



Marginal Cost

Figure 3. Welfare loss due to consumer moral hazard (dotted area).

Producer moral hazard, on the other hand, occurs when physicians prescribe more drugs than they would in the absence of insurance coverage.<sup>58</sup> Since physicians are not paying for the pharmaceuticals, they have no reason to limit their usage. For example, assume a patient has a headache and a physician can recommend one of two remedies, a cheap over-the-counter (OTC) drug or an expensive prescription, and each remedy will have equal

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<sup>57</sup> See id.

<sup>58</sup> See id.

effectiveness. Though the most efficient choice is to recommend the OTC drug, the physician is at best indifferent to the choice.

Producer moral hazard is amplified by indemnity insurance since most insurance plans operate under a fee-for-service (FFS) reimbursement system.<sup>59</sup> Under this type of reimbursement, insurance companies reimburse a physician every time a patient comes in for an office visit. A FFS program creates a financial incentive for doctors to maximize the number of office visits by patients. Since office visits concerning pharmaceuticals are relatively short and easy, prescribing unnecessary prescriptions is often a very convenient method of generating extra income. Therefore, physicians in FFS programs tend to prescribe pharmaceuticals in excess of the quantities they would prescribe if they were paid just a fixed salary.<sup>60</sup> While producer moral hazard occurs even in the absence of indemnity coverage, indemnity coverage magnifies the effect because the doctor knows the patient will not have to pay the cost of the increased services and also because the patient has little incentive to restrain the physician's behavior.

Producer moral hazard is also termed supplier-induced demand (SID).<sup>61</sup> This supplier-induced demand has the effect of shifting the observed demand curve to the right of what the true demand is. Some patients are now not demanding the drug because of the benefits to themselves, but because the physician prescribed it. This effect is illustrated graphically in **Figure 4**. The lined area represents the additional welfare loss created because these consumers would not have taken the drug in the absence of the effects of producer moral hazard.

Observed Demand Curve

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<sup>59</sup> See *id.*

<sup>60</sup> See *id.*

<sup>61</sup> See *id.*

Actual Demand Curve

Price



Price paid by insurer

Marginal Cost



Quantity

Figure 4. Additional welfare loss due to producer moral hazard (red lines).

Thus, both types of moral hazard lead to an increased consumption of pharmaceutical drugs – in other words, there is an “artificial demand” for drugs. This artificial demand creates a distortion in the pharmaceutical market because the excess consumption of drugs leads to higher total revenues than the pharmaceutical company would be able to collect in a market with no insurance coverage.<sup>62</sup> This is illustrated graphically in **Figures 3 and 4**; the total revenue collected by the drug companies (all colored area) is greater than the resulting total revenue under the Ramsey model in **Figure 2**. Consequently, pharmaceutical companies collect more revenue than the total social benefit of the drug.<sup>63</sup> This will cause pharmaceutical companies to invest more money than is socially optimal into research and development – a behavior termed “rent-seeking”. This is economically inefficient because companies will develop drugs that have a net social loss – the development cost outweighs the corresponding social benefit.

The overconsumption of prescriptions is a price-neutral effect of moral hazard. Moral hazard also has a

<sup>62</sup> The Ramsey differential model yields the highest revenue a pharmaceutical company can collect in a free market because theoretically the revenue collected equals the total social surplus created by the drug.

<sup>63</sup> In Figure 4, the total revenue, which is the sum of the colored areas, is greater than the area under the demand curve.

direct effect on the price drug companies will charge. In a market with no insurance coverage, the price a pharmaceutical company charges is constrained by the patient – a patient will only pay for a pharmaceutical if the cost is less than the patient’s valuation. However, in the presence of indemnity insurance, the patient is completely indifferent to cost of a drug. Pharmaceutical companies can charge higher prices than they could under normal market conditions because consumers do not have an incentive to discipline these prices. This behavior will lead to higher revenues for pharmaceutical companies and consequently there is once again the risk of excessive rent-seeking.

*Combating overconsumption caused by moral hazard*

There is a strong incentive to constrain moral hazard so as to reduce welfare loss and prevent excessive rent-seeking. However, efforts by insurers to limit moral hazard are restrained by informational asymmetries.<sup>64</sup> For example, insurance plans could constrain moral hazard by monitoring prescription usage more carefully. However, the benefits of monitoring are low compared to the costs. Even if an insurer monitors every prescription, the insurer has no way of predicting how a particular patient would have behaved in the absence of insurance coverage. Similarly, the benefits of monitoring producer moral hazard are limited because it is difficult to determine when a physician is legitimately prescribing a medicine and when he is just prescribing one to increase profits.

In the alternative, one cost-effective method for restraining consumer moral hazard is the use of expense pass-throughs, such as deductibles and co-payments. This strategy combats consumer moral hazard by increasing the patient’s out-of-pocket cost for each prescription. Imposing an out-of-pocket expense decreases

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<sup>64</sup> See *id.*

the welfare loss associated with insurance coverage<sup>65</sup>, as illustrated in **Figure 5**. The out-of-pocket payment convinces some users who would otherwise have taken the drug to not consume it. The drawback to pass-throughs is that there is a limit to how much insurers can charge patients out-of-pocket; as out-of-pocket expenses increase, the amount of insurance protection decreases. Thus, pass-throughs are effective at discouraging frivolous drug usage, but there is still a significant welfare loss even with pass-throughs in place.

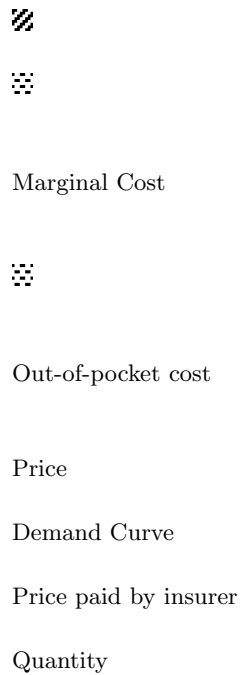


Figure 5. Reduction in welfare loss due to out-of-pocket expenses (yellow lines).

<sup>65</sup> The amount of decrease is represented by the lined area.

In contrast, a strategy for combating producer moral hazard involves altering a physician's financial incentives. If a physician does not bear any of the costs associated with prescribing a drug, the physician has no incentive to perform a cost-benefit analysis concerning the drug. Insurers can alter a physician's financial incentives in several ways. Insurers can eliminate the incentive to increase office visits by providing the physician a fixed salary. They can also alter the physician's financial incentives by making physicians personally liable for drug costs if the physician prescribes more drugs than a pre-set limit. However, these methods also have their drawbacks. Limits on physician prescriptions create a conflict of interest for the physician; the doctor now has a financial incentive to not provide proper care to the patient. If these controls are too stringent, they have the effect of lowering demand beyond the point of true demand. Then some people who really need the drugs will be denied access. These and other methods for controlling both consumer and producer moral hazard are discussed more fully later.<sup>66</sup>

While all three of the above methods – monitoring, expense pass-throughs, and physician incentives – reduce moral hazard somewhat, none of these methods can eliminate the welfare loss created by moral hazard. Due to informational asymmetries, monitoring is a not a very effective method at reducing moral hazard. Increasing out-of-pocket expenses reduces consumer moral hazard, but there is a limit to the expenses that patients are willing to bear. Physician incentives can also reduce moral hazard, but these systems are expensive and also create a conflict of interest for treating physicians. However, there is one other method by which insurers can reduce the welfare loss associated with moral hazard.

## Combating pricing effects of moral hazard

The other primary method by which insurers can combat moral hazard is by negotiating lower prices. As illustrated

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<sup>66</sup> See *infra* Part III.

in Figure 6, the more an insurer can lower prices, the more it can reduce the welfare loss associated with insurance coverage.<sup>67</sup> Taken to an extreme, this means that insurers should price pharmaceuticals down to their marginal cost because this will result in the lowest welfare loss. However, as stated earlier, this is unacceptable to pharmaceutical companies because then they cannot recover the sunk costs associated with a drug's development.



Original Price

Lower Price



Marginal Cost



Out-of-pocket cost

Price

Demand Curve

Quantity

Figure 6. Reduction in welfare loss due to lower price (yellow lines).

In a competitive market, where there are multiple insurance companies and multiple pharmaceutical firms, an insurer will negotiate with a pharmaceutical company and ostensibly the two will come to a mutually agreeable

<sup>67</sup> The amount of decrease in welfare loss is indicated by the lined area.

price. The pharmaceutical company has a monopoly on production of the drug and the insurer has no other way to acquire the drug. If the insurer does not cover enough of the drugs in demand, patients will leave and go to another insurance company. On the other hand, the insurer is paying the cost of the prescription and has control over which prescriptions it will choose to reimburse. If the pharmaceutical company cannot convince the insurer to cover the cost of the prescription, its sales will significantly drop. With the presence of these two countervailing market pressures, the market will reach an optimal equilibrium price.

However, these same market pressures do not apply in the case of a single-payer system. A single-payer system has significantly more market power than a pharmaceutical company, granting it much greater negotiating leverage. The single-payer system is a monopoly – it is the only insurance company in the country. This position gives it significant market power since the system provides the pharmaceutical company's only access to consumers in that country. While the patent system grants a pharmaceutical company a limited monopoly, the company does not have the same market power as the single-payer system. The pharmaceutical company has many competitors that the single-payer system can negotiate with and these competitors most likely have comparable substitutes. Even if a pharmaceutical company has a truly unique product, the single-payer system can exert market power by refusing to reimburse other products that the company produces.

In addition to market power, single payer systems are able to exert even more negotiating leverage through the threat of compulsory licensing.<sup>68</sup> Through a compulsory license, a foreign sovereign can nullify a pharmaceutical company's patent monopoly and grant another company the right to manufacture a generic version of the drug. Since the generic manufacturer does not have to recoup the huge sunk costs that the original manufacturer incurred, the generic drug can be priced significantly below the brand name version. Though a government's right to impose a compulsory license is somewhat limited by the TRIPs agreement, it is still nevertheless a significant

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<sup>68</sup> See, e.g., *U.S. sets hearing on Abbott AIDS drug license*, FORBES.COM (April 28, 2004), at <http://www.forbes.com/business/newswire/2004/04/28/rtr1351822.html>.



threat.

With the combination of greater power market and the threat of compulsory licensing, a single-payer system it is able to wield significantly greater negotiating leverage than pharmaceutical companies. In effect, the single-payer plan can set prices at whatever reasonable level it chooses without fear of retaliation from a pharmaceutical company – a real negotiation never takes place. Of course pharmaceutical companies still have some power. For example, a pharmaceutical company can delay the introduction of a new drug into a market. Further, pharmaceutical companies can also exert leverage on government officials through lobbying, especially on elected officials. However, none of these alternatives can match the power of a sovereign purchaser.

With its superior negotiating leverage, a sovereign government has the power to price a drug almost as low as it wishes. It is also has significant incentives to set the price as low as possible, because that will reduce health care expenditures and minimize the welfare loss associated with moral hazard. However, at the same time, a sophisticated government should realize the detrimental effects of such strict pricing. If a pharmaceutical company cannot recover the sunk costs of R&D, then the company will not have an incentive develop other life-saving drugs. Therefore, a sovereign government must determine an optimal pricing scheme under which it can balance the benefits of reducing prices with the need to maintain incentives for future research.

A government can achieve this goal by trying to balance the two market distortions created by a single-payer system. The welfare loss associated with moral hazard is a negative externality while the deadweight loss created by uniform pricing is a positive externality. As illustrated in Figure 7, a single-payer system can restore optimal pricing for a drug by balancing the increased revenue from moral hazard (dotted area) with the decreased revenue from uniform pricing (lined area). If the two externalities cancel each other out, then the sovereign government ensures that the pharmaceutical company will still be able to collect total revenue equal to the social surplus

created by the drug. The same market incentives that existed under the Ramsey pricing model are maintained. Since total revenue equals the social surplus, pharmaceuticals companies will develop all drugs with a net social surplus and will avoid the development of drugs with a net social deficit – which maximizes economic efficiency.



Price paid by insurer



Marginal Cost

Out-of-pocket cost

Price

Demand Curve

Quantity



Figure 7. Optimal pricing under a single-payer system. The blue dotted area representing increased revenue from moral hazard approximate equals the blue lined area representing dead-weight loss.

## 5. Avoidance of joint costs under a single-payer system

As discussed above, cost controls are economically beneficial since they address distortions in the prescription drug market that arise from a single-payer system. When imposing a cost control, a sovereign will ensure that

the amount of revenue collected by pharmaceutical companies equals the social benefit created by the drug. This allows for a more efficient allocation of capital and ensures that drug companies only market drugs with a net positive social surplus. However, the previous model assumed a closed-market system – that is, one where there are no imports or exports. When a single-payer system is placed in the context of a global marketplace, the government's behavior will change. A global pharmaceutical marketplace creates a free-rider problem that encourages a single-payer system to price drugs at a level lower than it would in closed-market system.<sup>69</sup>

The drug industry spends more than \$800 million in research and development for every drug brought to market.<sup>70</sup> These costs are joint costs – they do not depend on the number of people using a drug. These joint costs are essential to production of a drug, but cannot be isolated to any particular customer or country.<sup>71</sup> While the costs cannot be attributed to any country, the benefits accrue to all countries.

Since the benefits of research accrue to all countries, a “defecting” country can choose not to contribute any of its own money to research<sup>72</sup> and still share in the benefits of research conducted by other countries. The failure of this defecting country to not contribute to the joint costs of R&D will slightly reduce global incentives for research, but if this is an isolated case there, will not be a large impact on global research. The defecting country will then be able to share in benefits of global research without making its own contribution to global research – it will be a “free rider”.<sup>73</sup> The effects of this behavior when there is one free rider are illustrated in Figure 8.



Defecting country

<sup>69</sup> See Russell Hardin, *The Free Rider Problem in* STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Edward N. Zalta ed. Summer 2003 edition), at <http://plato.stanford.edu/entries/free-rider/>.

<sup>70</sup> See DiMasi, *supra* note 11, at 169.

<sup>71</sup> See DANZON, *supra* note 12, at 3.

<sup>72</sup> By pricing drugs at the cost of production.

<sup>73</sup> See Hardin, *supra* note 69.



Marginal Cost

Demand Curve

Price



Quantity

Figure 8. Revenue loss associated with a free-rider.

A free rider problem occurs when one economic actor can benefit from a good or service provided others without contributing to that good.<sup>74</sup> Thus, each actor has an incentive to allow others to pay for the public good and to not personally contribute for the public good. Consider an international marketplace of twenty countries, each with a single-payer system. Country A realizes that only a portion of the money it contributes to global R&D accrues to its own benefit. The rest of the money is spread between the other twenty countries. Thus, country A's incentive is to minimize its contribution to R&D because other countries are benefiting more from the research than it is. Of course, each of the other nineteen countries has the same financial incentives as Country A. Thus, they too will impose price controls that reduce their contribution to R&D. The resulting equilibrium is that no country contributes to joint R&D and no country is able to reap the benefits of pharmaceutical innovation.

A free rider problem is a variant of an n-person prisoner's dilemma scenario.<sup>75</sup> While the maximum socially beneficial point is where all the market participants contribute, the threat of the other players "defecting" forces all market participants to also defect. In a prisoner's dilemma, not contributing is termed the "dominant strategy"

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<sup>74</sup> See id.

<sup>75</sup> See id.

because regardless of what the other players choose, Country A is always better off if it defects. For example, if all the other countries choose to contribute, then Country A is better off defecting because it can free ride off of the other countries' contribution with no cost of its own. On the other hand, if all other countries defect, then A is better off defecting because otherwise it will be the lone "sucker" that is paying for R&D while everyone else will free-ride off of its contribution.

The prisoner's dilemma is an example of a private market failure. Private markets do not provide a way to resolve the economic inefficiency created by this scenario. Instead, resolving a prisoner's dilemma requires the economic actors to forego their normally competitive stances and to agree to cooperate to resolve the dilemma. This type of prisoner's dilemma is not unlike the dilemma faced in international trade. While all countries are better off if all countries open their borders, the maximum benefit derives to Country A if it keeps its borders closed and every other country opens of its border. Removing international trade borders has required a lot of patience and also has required multinational cooperation through treaties such as the General Agreement on Trade and Tariffs (GATT) and later through multinational organizations such as the World Trade Organization (WTO).

While the above example was a hypothetical, as we will see later,<sup>76</sup> Americans feel that there is sufficient evidence that other countries are trying to avoid joint costs and free ride off of U.S contributions. Just as with international trade, if the full benefits of new pharmaceutical discoveries are to realized, all countries must join together and develop an international understanding concerning pharmaceutical research.<sup>77</sup> Due to the prisoner's dilemma, individual countries thinking only of their own welfare have no economic incentives to avoid defecting. Further, due to the imbalance of market powers,<sup>78</sup> pharmaceutical companies do not have the ability to police this dilemma either. The only resolution to this dilemma is international cooperation. This paper outlines a possible structure

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<sup>76</sup> See *infra* Part IV.

<sup>77</sup> At least all industrialized countries, since they are most able to pay the joint costs of research.

<sup>78</sup> See *supra* Part II.4.

for just such an international later in Part V.<sup>79</sup>

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<sup>79</sup> See *infra* Part V.

### Part III. International price control regulations and their effectiveness.

Almost every foreign country has a single-payer health care system. These systems all impose some type of cost control mechanisms on prescription drug spending. This Part will detail some aspects of price controls in each country and will try to determine the effects of these regulations on international research and development. As we will see, countries use price mechanisms to accomplish various goals, such as promoting domestic economic growth or capping spending at certain predetermined budget targets. However, none of these cost control schemes are designed to look at the costs associated with developing pharmaceuticals and fairly compensate drug companies for their research expenditures.

#### 1. Domestic and foreign price control regulations

##### **French direct price regulation**

France has resorted to using direct price controls in order to hold down costs.<sup>80</sup> The prices of new products must be approved before the product is launched and increases in prices must also be approved. Otherwise, the drugs will not be covered by the government insurance. The price control regulations are based on several criteria. France regulates prices based on comparisons within a therapeutic group, therapeutic merit, and contribution to the domestic economy. Therefore, the government allows a higher rate of reimbursement for pharmaceuticals that are produced domestically.<sup>81</sup> Often, the government will impose across the board price cuts. Further, the

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<sup>80</sup> See DANZON, *supra* note 12, at 16.

<sup>81</sup> See *id.* at 17.

government applies a comprehensive revenue limit on certain popular drugs – regardless of the volume of that drug sold, the total reimbursements associated with that drug cannot exceed a certain preset budget.<sup>82</sup>

## Canadian comparative price regulation

Canada also imposes direct price controls – however, Canada uses different criteria to determine price.<sup>83</sup> The reasonableness of prices is determined by comparing the price charged in Canada with the median price of the drug in nine other industrialized countries. If the drug has a therapeutic equivalent, reasonableness is determined by comparing the price to prices of other drugs in the same class. The government routinely reviews the prices of existing prescription medications to ensure they are still reasonable. Further, post-launch price increases cannot outpace the rate of general inflation. Before 1993, Canada reserved the right to issue a compulsory right for any drug that was overpriced.<sup>84</sup>

Unfortunately, neither the French nor Canadian schemes are aimed at calculating the global joint costs of research and allowing drug companies to recoup reasonable returns on their sunk costs. These price controls are often based on subjective factors and arbitrary political discretion<sup>85</sup>. The Canadian system is arguably more objective than the French. However, in practice, international comparisons are just as arbitrary due to the many factors in each country that may account for different prices. These factors include different purchasing power, different doses and unit sizes, exchange rates, distribution costs, advertising costs, liability expenses, and varying input costs for labor and materials.<sup>86</sup> Further, this type of comparative pricing scheme amplifies the effects of the free

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<sup>82</sup> See *id.*

<sup>83</sup> See *id.*

<sup>84</sup> See *id.*

<sup>85</sup> See *id. at 18.*

<sup>86</sup> See *id.*



rider problem. By comparing prices is anticipating the pricing dilemma and positioning itself so as to retaliate to any cost-cutting measures taken by other countries.

The French system is overtly biased towards favoring domestic drug products over foreign products. This government system has resulted in the development of imitative drugs that are designed to be sold only in the French marketplace. Commentators question whether the marginal benefits of these imitative drugs really outweigh their costs.<sup>87</sup>

### German cost control system: Reference pricing and physician budgets

The German health care system uses two primary forms of cost control. In the first form, reference pricing, the government divides drugs into classes with similar therapeutic properties.<sup>88</sup> The government then sets a single reimbursement rate for all drugs within the class. The reference price is set slightly higher than the lowest priced drug in the group so as to insure a sufficient supply of drugs.<sup>89</sup> The reference price for a product may be divided into subgroups to reflect different dosages of a product as well as a diverse means of delivering the product (e.g., by way of a topical patch as opposed to sublingual). In theory, producers are free to charge a price above the reference price – patients would then be required to pay the difference as an out of pocket expense.<sup>90</sup> Realistically, patients' reluctance to make excess payments makes the price of a drug highly elastic above the reference price.<sup>91</sup>

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<sup>87</sup> See *id.* at 44.

<sup>88</sup> See WERTHEIMER, *supra* note 19, at 165

<sup>89</sup> See *id.*

<sup>90</sup> See DANZON, *supra* note 12, at 19.

<sup>91</sup> See *id.*

Reference pricing thus provides strong incentives for a company to price its product at the reference price. While reference pricing thus invokes strong competition for prices above the reference price, there is no incentive for price competition below the reference price.<sup>92</sup> This system is designed to address consumer moral hazard. By making consumers liable for excess costs, they have an incentive to buy the lowest price drug.<sup>93</sup> In theory this would then combat the problem of consumer moral hazard by requiring consumers to weigh the costs and benefits of a drug.

However, in practice the effect of this type of regulation is that all drugs are priced the same, regardless of effectiveness. Thus, the regulation really has a negative impact because equal pricing destroys the incentives to invest large amounts in R&D to develop innovative drugs.<sup>94</sup> Also, since there is no price competition below the reference price, this system discourages the use of generic medicines.<sup>95</sup> The equalization of prices destroys market discipline which can lead to an inefficient allocation of capital.

Germany also employs a physician drug budget system.<sup>96</sup> Under this system, the government regularly audits a physician and evaluates his or her prescription history. Each physician's total drug costs are compared against a preset government "norm". Physicians that exceed their norm by more than a set amount may face repayment of the excess costs.<sup>97</sup>

Physician drug budgets adopted in Germany appear to have significantly decreased drug spending.<sup>98</sup> The German

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<sup>92</sup> See *id.*

<sup>93</sup> See *id.* at 20.

<sup>94</sup> See *id.* at 50.

<sup>95</sup> See *id.* at 20.

<sup>96</sup> See WERTHEIMER, *supra* note 19, at 165.

<sup>97</sup> See *id.*

<sup>98</sup> See *id.* at 166

system significantly reduces producer moral hazard by requiring doctors to share in the cost of health care coverage.<sup>99</sup> Physicians have less of an incentive to over prescribe drugs since they could be personally liable for any excessive costs. This forced accountability appears to have slowed the rate of increase in drug spending, as well as lowered the overall number of prescriptions issued.<sup>100</sup> This type of regulation results in lower costs in a price-neutral fashion. Thus, it results in more economically efficient decision-making. Conversely, the drawback of these budgets, as discussed previously,<sup>101</sup> is that if there is not enough flexibility, the controls can go too far and discourage the use of drugs when it is economically efficient.

## American cost control strategies

American insurers employ a variety of cost containment strategies including manufacturer discounts, drug formularies, and forced generic substitution.<sup>102</sup> Health plans incorporate cost controls with the help of a Pharmacy Benefit Manager (PBM). Smaller health plans contract with private PBMs while larger health plans will have their own inhouse PBM. These PBMs are able to negotiate discounted prices with drug manufacturers.<sup>103</sup> These discounts take the form of manufacturer rebates. The range of these discounts is confidential, but experts estimate they range from 2% - 35%.<sup>104</sup>

Most PBMs also reduce the cost of prescription drugs through the use of formularies.<sup>105</sup> A formulary is list of drugs that the insurer will reimburse. The insurer will only reimburse drugs on that list. Insurers typically use a committee of physicians to evaluate and weigh certain factors such the dosage, side effects, efficiency, and cost of

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<sup>99</sup> See *id.*

<sup>100</sup> See *id.*

<sup>101</sup> See *supra* Part II.

<sup>102</sup> See STUART O. SCHWEITZER, PHARMACEUTICAL ECONOMICS AND POLICY 104, 121 (1997).

<sup>103</sup> See HHS, *supra* note 4.

<sup>104</sup> See *id.*

<sup>105</sup> See SCHWEITZER, *supra* note 102, at 121.

a drug.<sup>106</sup> The insurance company uses the formulary as leverage to help negotiate lower prices; pharmaceutical companies will lower prices to ensure they are on an insurer's formulary. Often, the formulary will consist of a tiered structure. Under this structure, customers pay a minimal copayment for generic drugs. Then the formulary will create two tiers of private drugs. The drugs on the lower tier require a smaller co-payment than the drugs on the higher tier.<sup>107</sup>

Formularies help combat consumer moral hazard. By charging consumer different fees for drugs, formularies steer patients towards the most effective and least costly drugs. However, because drugs affect patients in different ways, formularies must contain a wide variety of drugs and retain the flexibility to take special situations into account.<sup>108</sup> Statistical studies demonstrate the effectiveness of these systems at controlling drug costs.<sup>109</sup>

Finally, PBMs often impose forced generic substitution.<sup>110</sup> This requires patients to use a generic drug whenever it is available. PBMs encourage the use of generic drugs because they cost less than brand-name versions of a drug and yet they are chemically and therapeutically similar to the brand-name drug.<sup>111</sup> This type of measure fights consumer moral hazard because it steers consumers to the most cost-effective version a drug.

## The British system: rate of return regulation

The United Kingdom employs a scheme that regulates profits rather than regulating prices. Every five years, representatives from the Association of the British Pharmaceutical Industry meet with representatives from the British Department of Health and the two sides negotiate a compromise that meets the cost control requirements of the

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<sup>106</sup> See *id.*

<sup>107</sup> See *id.* at 122.

<sup>108</sup> See *id.*

<sup>109</sup> See Brenda Motheral and Kathy A. Fairman, *Effect of a three-tier prescription copay on pharmaceutical and other medical utilization*, 39 MEDICAL CARE 1293 (2001).

<sup>110</sup> See SCHWEITZER, *supra* note 102, at 122.

<sup>111</sup> See *id.*

government while meeting the profit demands of pharmaceutical companies.<sup>112</sup> The negotiated Pharmaceutical Price Regulation Scheme (PPRS) limits the maximum total rates of return on capital (ROC) that pharmaceutical companies are able to earn for all products sold to the national health care system. Though the negotiations are purely voluntary, every major government customer participates.

Under the scheme, every year companies submit a form that details their annual sales, costs, profits, and deployment of capital. The company's deployment of capital is considered to be the value of each company's research, manufacturing and distribution facilities within the country. The costs includes the company's share of general and administrative expenses, manufacturing overhead, costs of good, research expenditures, and advertising costs. However, the costs only include the share of costs expended in the country and attributable to sales in that country. The government further sets limits on the amount of advertising and research expenditures that can be considered as costs.

Companies then individually negotiate their allowed ROC with the government, which is usually between 17 and 21 percent. Each company's allowed ROC is determined on factors such as the amount of exports and the percent of manufacturing and R&D carried on in the U.K.<sup>113</sup> The government then looks at each company's profits and determines if it has exceeded its allowed ROC. Excess profits are allowed if they are with a certain gray area. However, if the profits are too high, the company must undergo measures to bring the profits back in line with the allowed ROC, such as returning profits to the government or cutting prices.<sup>114</sup>

Under the PPRS, pharmaceutical firms are free to set their own prices when a product is launched. However, after that point companies cannot raise prices without approval of the government. The government will only

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<sup>112</sup> See ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY (ABPI), DEPARTMENT OF HEALTH DISCUSSION PAPER: THE PHARMACEUTICAL PRICE REGULATION SCHEME (September 2003), available at <http://www.abpi.org.uk/information/pdfs/PPRS-ABPI-Response-To-DOH.pdf>.

<sup>113</sup> See Ronald T. Rapp and Adam Lloyd, "Civilized" Pharmaceutical Price Regulations: Can the U.S. have it too?, REGULATION: THE CATO REVIEW OF BUSINESS AND GOVERNMENT, at <https://www.cato.org/pubs/regulation/regv17n2/reg17n2-rapp.html>.

<sup>114</sup> See DEPARTMENT OF HEALTH, THE PHARMACEUTICAL PRICE CONTROL SCHEME (July 1999), available at <http://www.dh.gov.uk/assetRoot/04/01/99/93/04019993.pdf>.

allow price increases if a company's ROC falls below 8.5%.<sup>115</sup>

The British system is drastically different from some other stifling price schemes, such as the one used in France. The PPRS actively encourages domestic R&D spending by allowing pharmaceutical companies to make a profit on their drug sales in the Britain. However, the government sets reasonable limits on the profits to limit the enormous costs of pharmaceuticals on the domestic budget.

While the British system encourages domestic R&D, it blatantly discriminates against foreign R&D. British profit regulation is based on a return on domestic capital.<sup>116</sup> The basic rule is not based on the amount of sales the company does. Thus, foreign subsidiaries doing business in Britain, who usually have little capital invested in the country, are not able to make a significant return on sales. The PPRS does provide for an alternative Return on Sales (ROS) approach for these types of companies. However, under the ROS, a company is only allowed to earn a fixed profit of 4.85% on its U.K., with no allowed gray area.<sup>117</sup> Thus the system is blatantly biased in only allowing a reasonable return on research performed within the country. Even for large multinational companies with significant assets in Britain, it is difficult to collect royalties for research done overseas due to restrictions on transfer pricing.<sup>118</sup> Basically, the agreement favors domestic drug companies over foreign competitors.

This agreement is a direct consequence of the prisoner's dilemma associated with pharmaceutical research and development. While research done overseas has significant benefits in terms of British health, the British are unwilling to pay the cost of such research. They are only willing to fund research if there is contribution to their economy. Even given the contribution to their economy, the British will only fund research up to a certain preset limit and will only allow limited profits on that research. These regulations preserve incentives for domestic R&D,

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<sup>115</sup> See *id.*

<sup>116</sup> See *id.*

<sup>117</sup> See *id.*

<sup>118</sup> See *id.*

but they have detrimental consequences for research overseas.

Britain uses further cost controls like capitation compensation for physicians and the use of drug budget scheme like the one in Germany.<sup>119</sup> The government also encourages the use of generic pharmaceuticals through the implementation of a drug tariff. The tariff provides a financial incentive to physicians to prescribe generic drugs.<sup>120</sup>

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<sup>119</sup> See DANZON, *supra* note 12, at 22.

<sup>120</sup> See *id.* at 21.

## IV. Drug reimportation proposals.

When looking at the price controls in many other countries, American citizens feel they are being taken advantage of. For example, Britain only allows a return on domestic capital and investment – pharmaceutical companies cannot take the cost of American or other foreign R&D into account when determining the price to sell there.<sup>121</sup> The price control regulations explicitly allow Britain to avoid paying for its share of global joint R&D costs. Considering that many countries have prices even lower than Britain's,<sup>122</sup> there are probably other countries that are also avoiding the joint costs of R&D.

This is an outgrowth of the free rider problem considered earlier.<sup>123</sup> The United States is the largest country without price controls. The U.S. accounts for more than 54% of worldwide pharmaceutical sales and even a larger proportion of profits.<sup>124</sup> Further, U.S. prices are significantly higher than prices overseas, even when accounting for local factors affecting the price of drugs.<sup>125</sup> Accordingly, Americans feel they are unfairly paying for drugs that are used all over the world. Other countries are free-riding on the benefits of American pharmaceutical research investments. In order to neutralize the price disparities between American and overseas markets, many policymakers want to pass a bill that will allow the reimportation of drugs from overseas back into the U.S.

The reasoning behind making reimportation of drugs from other nations legal is that competition from lower cost imported pharmaceuticals will force companies to lower prices in the U.S. Currently, the 1987 Prescription Drug Marketing Act<sup>126</sup> restricts reimportation of foreign drugs into the US due to safety concerns. However, analysts

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<sup>121</sup> See *supra* Part III.

<sup>122</sup> See DANZON, *supra* note 12, at 31.

<sup>123</sup> See *supra* Part II.

<sup>124</sup> See Scheherazade Daneshkhu, *US closer to battle with Europe over drug prices*, FINANCIAL TIMES.COM (May 14, 2004), at <http://news.ft.com/servlet/ContentServer?pagename=FT.com/StoryFT/FullStory&c=StoryFT&cid=1083180526584>

<sup>125</sup> See CBO, *supra* note 7.

<sup>126</sup> Pub. Law No. 100-293.



believe that these safety concern can be overcome and that reimportation is a viable option.<sup>127</sup>

On December 8, 2003, President passed into law the Medicare Prescription Drug, Improvement, and Modernization Act.<sup>128</sup> The bill primarily provides a prescription drug benefit plan for senior citizens. However, included in the bill is a provision allowing pharmacists, wholesalers, and customer to reimport drugs from Canada, but only if the Secretary of Health and Human Services establishes guidelines under which he can certify the practice is safe.<sup>129</sup> Secretary Thomson has already stated that he does not believe the practice of reimportation is safe with current resources and so he will not be able to create a feasible plan for reimportation.<sup>130</sup>

Several months ago, the House passed a much more comprehensive bill allowing the reimportation of pharmaceuticals from 25 other industrialized countries.<sup>131</sup> A similar bill was introduced in the Senate a few months ago, but failed to pass.<sup>132</sup> However, due to increased pressure from voters and the upcoming elections, many Senators who were previously opposed may reconsider their position.<sup>133</sup> A bill similar to the House bill was very recently reintroduced in the Senate.<sup>134</sup> In a recent interview, the Secretary of Health and Human Services (HHS), Tommy Thompson, acknowledged that while he is still opposed to drug reimportation, adoption of the idea is politically inevitable and George Bush should not stand in the way.<sup>135</sup>

Drug reimportation may help end the trend of Americans subsidizing drug production for the rest of the world. However, the bill does not establish a system whereby drug companies will be able to recover their sunk costs. Maybe, after the reimportation bill has been passed, drug companies might be forced to raise their prices elsewhere. While this is a possibility, it is unclear that drug companies have the political clout overseas to force

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<sup>127</sup> See Schuler, *supra* note 9.

<sup>128</sup> Pub. Law No. 108-173.

<sup>129</sup> See *id.*

<sup>130</sup> See Schuler, *supra* note 9.

<sup>131</sup> H.R. 2427, 108th Congress (2003).

<sup>132</sup> See Schuler, *supra* note 9.

<sup>133</sup> See *id.*

<sup>134</sup> S. 2307, 108th Congress (2004).

<sup>135</sup> See Bush Administration reconsidering Canadian drugs, YAHOO!NEWS (May 7 2004), at [http://news.yahoo.com/news?tmpl=story&u=/ibsys/20040507/lo\\_wisc/2196499](http://news.yahoo.com/news?tmpl=story&u=/ibsys/20040507/lo_wisc/2196499).

governments to drop price controls. Further, price controls will have the effect of homogenizing drug prices across the industrialized countries. This homogenization of prices is directly contradictory to the price discrimination policy developed by Frank Ramsey.

Congress wanted to find a market solution to the drug price crisis,<sup>136</sup> however, drug reimportation merely imports price controls from other countries – it would be the same as imposing controls ourselves. Thus all countries will now avoid paying their share of research expenses and drug research will be stifled. The only way to achieve true international parity in prices is to assure that all countries are paying their fair share of drug development costs. The only way to solve the issue of international joint sunk costs is through some international agreement or treaty, similar to the TRIPs agreement in WTO.

The investigative arm of Congress, the Congressional Budget Office (CBO), further weighed in on the debate over reimportation by recently releasing a report that criticizes the proposal.<sup>137</sup> According to the agency, bringing in drugs from 25 industrialized nations under the House Bill would only reduce spending on medications in the United States by about 1 percent. The CBO pointed out that supply limitations, contractual limitations imposed by pharmaceutical firms, and the potential for foreign governments to take action blocking exports to the United States would limit the actual number of prescriptions that will be redirected to the U.S. market. The small trickle of drugs coming into the market will have little effect on U.S. prices.<sup>138</sup>

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<sup>136</sup> See *Schuler, supra note 9*.

<sup>137</sup> See CBO, *supra note 7*.

<sup>138</sup> See *id.*

## Part V. International treaty for sharing sunk costs.

Since the drug reimportation provision in the new Medicare Act will not effectively allocate the global joint costs of pharmaceutical development, this section outlines the elements of a new international framework that can equitably distribute these joint costs. As discussed earlier, recovery of the joint costs associated with pharmaceutical research and development presents the classic prisoner's dilemma.<sup>139</sup> A government can be easily tempted by the option of pricing prescription drugs down to marginal cost and allowing other countries to bear the costs associated with research and development. Pharmaceutical companies themselves do not have the negotiating leverage to deal directly with foreign governments. Since pharmaceutical companies do not have the market power to combat the threat of foreign compulsory licenses, fairly distributing pharmaceutical joint costs requires the mutual cooperation of the countries benefiting most from pharmaceutical research and development.

Unless the industrialized countries come to an agreement concerning prescription drug pricing regulations, individual regulations in each country will hamper efforts to recover the sunk costs of drug development. If drug companies are unable to recover their sunk costs, investment in drug development will decrease and many life-saving and cost-saving therapeutics will be prevented from coming to market. The international community must come together and ensure fair pricing for pharmaceuticals. Unless each country monitors its neighbors, governments have too strong of an incentive to price pharmaceuticals below the point where sunk costs can be recovered. Since the United States, Europe, and Japan represent the three largest pharmaceutical markets and account for the lion's share of revenue for the largest multinational drug companies, any international framework regulating prescription drug costs will require their approval. However, the benefits of the new treaty will be maximized if the other industrialized countries can be persuaded to sign on, and especially if developing nations can also be

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<sup>139</sup> See *supra* Part II.

persuaded to sign.

The proposed treaty will have a limited scope. It will focus on allowing companies to recover the sunk costs associated with the development of internationally-marketed drugs. Thus, the treaty will cover only patented pharmaceuticals, since these drugs are the most susceptible to regulatory abuse. Further, since the treaty addresses international sharing of costs, the treaty will only cover patented drugs that are marketed in at least three major international markets. These restrictions should help narrow down the scope and complexity of the treaty. Any international restriction on the use of cost controls must recognize that some cost controls are necessary and economically efficient. Therefore, the treaty will allow, and even encourage, the use of price controls aimed at reducing moral hazard while at the same time prohibiting regulations designed to merely avoid joint sharing of research costs. In practice, it can often be difficult to ascertain which regulations are desirable and regulations are not. Unfortunately, the treaty will necessarily have some ambiguity as to this question.

However, any international framework must be flexible and recognize the unique desires of participating governments. Some governments are willing to endure slightly higher drug costs if the prices will encourage domestic R&D investment. Further, every country takes a different approach to the benefits of widespread marketing and advertising. Finally, the treaty must recognize that prescription drug spending is straining every government's budget and thus some level of price control is absolutely necessary. Keeping all of the country-to-country differences in mind, however, the treaty must first and foremost ensure fairness among all countries. Most countries will be more willing to pay a slightly higher burden for prescription drug costs if an international framework ensures that other countries are providing their fair share of joint costs.

## 1. Outline of proposed international framework

This new international framework for regulating prescription drug costs is based on the British system of rate of

return regulation.<sup>140</sup> The new framework allows countries to impose reasonable profit limits, while other countries can avoid profit limits if they so desire. However, unlike the British system, this system ensures that joint research costs are shared globally in an equitable manner.

Under the framework, governments will not be able to directly set drug prices. Governments will only have the discretion to set some reasonable limits on drug profits. This treaty will provide a universal framework where each country can choose whether or not it wants to set some reasonable limit on pharmaceutical profits. At the same time, it ensures that no country sets a price cap so low that companies cannot recover joint R&D costs. Further, since the treaty only regulates drugs that are still patented, governments are free to exercise any cost restrictions on off-patent drugs, such as forced generic substitution.

Further, to avoid the dangers of governments exercising too much monopoly power, governments will not be able to negotiate directly with pharmaceutical companies nor will they be able to directly set prices unless profits exceed the predetermined cap. This means that governments will not be able to directly set drug prices nor could they require prior approval of a drug price before it is placed on a market. Governments also cannot impose any caps on drug price increases. In addition, under the treaty governments will not be able to implement regulations that have substantially the same effect as direct price control. An example of such a measure is reference pricing. While governments in reference pricing schemes do not directly set a drug's price, when the system is applied in practice, producers are usually forced to sell the drug at a price equal to the reference price reimbursement.

This restriction on the use of schemes that have substantially the same effect as price control regulations will introduce significant uncertainties into the treaty. There will also need to be a dispute resolution forum that can determine when cost controls cross the line from being reasonable to being unreasonable. This third-party could be a new multinational nongovernmental organization (NGO) formed for the express purpose of ensuring compliance

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<sup>140</sup> Discussed in Part III *supra*.

with this treaty. On the other hand, the third party could be a neutral arbitrator that is chosen when a dispute arises between treaty members. Despite the costs and uncertainties of third-party monitoring, a flexible provision that restricts the cost controls member nations can use is necessary. Without such a flexible prohibition of cost control schemes, nations would be able to easily circumvent the treaty and negotiate directly with pharmaceutical companies, thus undermining the purpose the new treaty.

Another example of the uncertainty inherent in the treaty will be the use of formularies. This is because formularies can serve a dual purpose. By creating different tiers of drug prices, formularies can steer patients towards the most cost-effective drugs. As discussed in the previous section, empirical research demonstrates the significant cost-saving benefits of a formulary system. However, the threat of not including a drug on the formulary or the threat of placing a drug on the highest tier can give national governments significant negotiating leverage. Therefore, the use of formularies will be allowed on a limited basis – governments will be allowed to develop formularies based drug effectiveness and based on cost-benefit analyses. However, under the new treaty, formularies cannot be used as a tool for governments to directly negotiate prices. Also, formularies cannot be used to favor domestic drugs over foreign drugs.

However, the treaty will allow governments some flexibility to control prices in their own governments. Drugs will be priced differently in each country based on the cost of business in that country and based on that country's share of international joint costs. Since price will be specific to each country, parallel drug trade, or the direct sale of prescription drugs from one country to another, will not be permitted under the plan. Citizens in each country must purchase drugs from domestic suppliers.

### 3. Hypothetical application of the concepts of the proposed international treaty

Prescription drug pricing is currently fraught with many complexities, and thus any treaty that attempts to standardize pricing across many countries will also be very complicated. However, the proposed system is easier

to understand when it is applied to a simple hypothetical example. In this example, there are two countries, the United States and the United Kingdom, and two pharmaceutical firms, Pfizer and Merck.<sup>141</sup> Both countries have signed the proposed international cost-sharing treaty. The United States has decided to impose a 30% cap on pharmaceutical rates of return. The United Kingdom, on the other hand, has decided to impose a 20% cap on pharmaceutical rates of return, the lowest cap allowed under the treaty. In addition, the U.K has imposed limits on pharmaceutical advertising; so advertising spending is much less there.

The limits on spending are allowed so that countries will be able to limit costs. Countries can set reasonable limits on any type of domestic expenditures.<sup>142</sup> There can even be a reasonable limit on the amount of domestic research allowed, as long as the country is paying its share of joint research costs. Further, a country can also set different maximum rates of return on each type of expenditure, as long as it still allows the minimum 20% return on each type. It can also discriminate between foreign and domestic research expenditures by allowing a return of higher than 25% on domestic research costs.<sup>143</sup>

The table below details expenditures and sales by the two pharmaceutical companies in each country.

Table 2. Hypothetical pharmaceutical pricing example with			
two coun- tries and two drug firms	Cost component		
	U.K.		
	Pfizer		

<sup>141</sup> All numbers are purely hypothetical.

<sup>142</sup> These are really spending limits, it is just a limit the maximum cost that the country will allow as an expense for determining return on capital.

<sup>143</sup> Again, as long as it still allows a 20% return on joint research costs.

	Sales (no. of pre- scrip- tions) <sup>144</sup>		
	Annual R&D costs	\$2,000	\$500
	Marketing costs	\$2,000	\$500
Merck			

	Annual R&D costs	\$1,000	\$1,000
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Cost of goods sold and distribution cost are \$1 per prescription			
U.K. per capita GDP is 90% of U.S. per capita GDP			

<sup>144</sup> Sales volume can not be determined by dollars of sales, since the treaty is used to determine the prices. Thus volume must be measured in number of prescriptions, number of doses, or number of pills. Since dosing varies country by country, measuring by the number of prescription is probably the best way to compare the benefits each country receives from a certain pharmaceutical.



Under the proposed treaty, Pfizer's R&D expenditures are allocated based on the number of prescriptions the company sold in each country. The number of sales in each country is adjusted based on some measure of income, such as per capita GDP. This income adjustment is one of the key aspects of the treaty. This ensures that R&D expenditures are allocated to countries in an equitable fashion based on which country is most able to share the burden. It is also an incentive for smaller to come on board and join the treaty. If a country's GDP is significantly lower than those of the big industrialized nations, it may easily be able to achieve cheaper prices under this treaty than it would without it.

Because the U.K.'s per capita GDP is 90% of U.S. per capita GDP, Pfizer's U.K. sales are discounted 10% from 500 to 450. Thus, Pfizer's total income-adjusted sales are 1,350.<sup>145</sup> Accordingly, Pfizer's sales are weighted 67% in the U.S. and 33% in the U.K.

Pfizer's total research expenditure in both countries is \$2,500. These research expenditures are allocated between the U.S. and the U.K. based on the income-adjusted sales ratio of 67% : 33%. So, \$1,667 of research expenditures are allocated to U.S. sales, and \$833 of research expenditures are allocated to the U.K. sales. For the 900 prescriptions Pfizer sold in the U.S., Pfizer has \$900 in manufacturing and distribution costs,<sup>146</sup> \$1,667 in R&D expenditures attributable to the U.S., and \$2,000 in marketing expenditures – for a total cost of about \$4,500. Further, Pfizer is allowed to make a maximum 30% return on those costs, which is a return of about \$1,400. Thus, the maximum revenue Pfizer is allowed to collect in the United States is the \$4,500 in costs plus the \$1,400 limit on returns. This means Pfizer faces a revenue cap of about \$5,900 and the highest average price Pfizer would be able to charge is about \$6.60 per prescription.

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<sup>145</sup>900 in the U.S. and 450 in the U.K.

<sup>146</sup>Based on the assumption of \$1 in manufacturing and distribution costs for each prescription.

However, because of the more stringent price restrictions in the United Kingdom, prices there will be significantly lower. For the 500 prescriptions Pfizer sold in the U.K., it has \$500 in manufacturing and distribution costs (based on \$1 per prescription), \$833 in R&D expenditures, and \$500 in advertising expenditures – for a total cost of about \$1,850. In the U.K., Pfizer is then allowed to make a 20% return on its cost – which is about \$350. For the year, Pfizer would be allowed to collect maximum sales revenue of about \$2,200 in the U.K., \$1,850 to recover its costs and \$350 as a return on those costs. This comes out to a price of about \$4.40 per prescription, which is 33% less than the cost of the same prescription in the United States. While Britain has achieved significant cost savings under the treaty, it has achieved those savings while ensuring that British citizens are contributing their fair share of the joint costs of drug development.

The same calculations can be performed for Merck. Merck has total income-adjusted sales of 1,350, only 450 of which are in the U.S. Thus, \$666 of Merck's \$2,000 R&D expenditures are allocated to the United States. Under the new treaty, Merck would be able to charge a maximum average price of \$7.50 per prescription in the United States<sup>147</sup> and a maximum average price of \$3.40 per prescription in the U.K.<sup>148</sup>

In reality, the price control regulations under this treaty will be look-back regulations. Using the Pfizer sales example from above, at the beginning of the year Pfizer would not know its exact costs and its exact sales in the U.K. It would have to approximate an appropriate price at the start of the year. At this time, Pfizer would be free to set any price it chose. Then, by the end of the year, Pfizer would calculate its relevant sales and cost information and submit it to the British government. The U.K. government would look at the company's revenue and retroactively determine whether Pfizer charged a reasonable price for its drugs. If Pfizer made enough revenue to give the company more than a 20% rate of return (in the hypothetical, if Pfizer had more than the \$2,150 in maximum allowed revenue), then the government could either require Pfizer to refund the extra revenue to its

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<sup>147</sup> Based on manufacturing costs of \$450, R&D expenses of \$666, marketing costs of \$1,500, and a 30% profit margin.

<sup>148</sup> Based on manufacturing costs of \$1000, R&D expenses of \$1,334, marketing costs of \$500, and a 20% profit margin.

customers, or force Pfizer to lower prices for the next year to compensate for the extra earnings.

This international framework is very similar to current British cost control regulations. However, under the current regulations, companies are only allowed to earn a return on research expenditures if the research occurs in Britain. This treaty means the British will face slightly higher prices than they would under their current system. For example, under the proposed treaty, Pfizer can charge as much as \$4.40 per prescription. Under current British regulations, though, Pfizer would only be able to recover \$500 for R&D expenditures rather than \$833 – and so Pfizer could only charge an average price of \$3.60 per prescription. The proposed treaty raises prices for British consumers because it ensures that British consumers are paying a share of international R&D expenses (adjusted for income) rather than just paying for domestic R&D expenditures.

Under the treaty, a country is permitted to take measures to encourage domestic research expenditures. A country that wants to stimulate domestic R&D can allow a higher rate of return on domestic R&D expenditures. Using the Pfizer example from above, the U.K. could decide to allow companies a 30% rate of return on domestic R&D while still capping returns on all other expenditures at 20%. Under this new scenario, Pfizer could earn a return of 30% on its U.K. R&D investment, but could only earn a 20% return on the excess \$333 of U.S. R&D expenditures attributed to the U.K. Pfizer could now a maximum average price of about \$4.50 in the U.K. If the British were to adopt this system, it would encourage Pfizer to shift more R&D expenditures to the U.K. in the future so as to raise the prices it can charge in that market. The U.K. would also benefit because the domestic R&D expenditures would stimulate domestic economic growth.

While the regulations under this treaty cap the maximum return that a drug company can earn, the regulations do not require that drug companies earn a minimum return on their investment. Though there are no limits on the ability of drug companies to raise prices, the companies will not be able to earn a guaranteed profit if governments research the cost-effectiveness of pharmaceuticals and steer patients towards the most beneficial

drugs. In this way, competitive market pressures will be restored because pharmaceuticals companies will be subject to market discipline. The product markets will determine a drug company's profits. Because rates of return are not guaranteed, drug companies will still have an incentive to spend money prudently and focus research on the most productive and innovative drug candidates.

#### 4. Summary

In summary, this treaty is designed to replicate the effects of the Ramsey pricing model on an international scale. If we assume that each country is a customer in the global marketplace for drugs, then the most efficient way to price pharmaceuticals is to charge each country a different price based on its willingness to pay. Since it is difficult to measure a country's willingness to pay, and given the high inelasticity of prescription drug prices, a good metric to measure the willingness to pay is to use the ability to pay. Accordingly, this treaty applies the Ramsey model to the international prescription drug marketplace by charging each country a different price based on its ability to pay. This will maximize revenue for the pharmaceutical companies and thus maintain incentives for future research. Further, it maximizes social welfare because the maximum number of countries will have access to life-saving drugs.



Marginal Cost

Demand Curve

Quantity

Price

Figure 9. Application of the Ramsey model to an international marketplace.